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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/943,441 | 08/30/2001 | Hai H. Trieu | 4002-2643 | 8143 |

7590 05/18/2004
Jason J. Schwartz
Woodard, Emhardt, Naughton, Moriarty and McNett
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Indianapolis, IN 46204-5137

EXAMINER

STEWART, ALVIN J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 09/943,441 | Applicant(s) TRIEU, HAI H. | |
| | Examiner Alvin J Stewart | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-25 and 48-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 9, 18, 25 and 70 is/are allowed.
- 6) ☒ Claim(s) 3-7, 10, 11 14-17, 19-24, 50, 53, 54, 56 and 58-69 is/are rejected.
- 7) ☒ Claim(s) 12, 13, 48, 49, 51, 52, 55 and 57 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claims 1, 2 and 26-28 are canceled. Claims 3-25 have been amended and new claims 48-70 have been entered.

Terminal Disclaimer

The terminal disclaimer has been accepted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 13, 50 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "inner fold surface" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 50 recites the limitation "said microtexturizing" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 67 recites the limitation "said polyurethane" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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Claims 3-7, 10, 11, 19-24, 50, 56, 58, 59, 63-66 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Lin US Patent 5,716,416.

Lin discloses an intervertebral disc comprising a body (see Fig. 1E) having a first end, a central portion, and a second end. The body elastically deforms from a first (see Fig. 1E) to a second configuration (see Fig. 4C). The first configuration has two ends mating with each other and at least one fold.

Regarding claims 5-7, see col. 2, lines 57-60.

Regarding claim 10, every surface has a texture. The texture will depend on the porosity of the material.

Regarding claim 11, every surface has a texture. With regard to claim 11, it is noted that the device of the Lin reference appears to be substantially identical to the device claimed, although produce by a different process, therefore the burden is upon the applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Regarding claim 19, see attachment.

Regarding claims 20, 21, 23 and 24 see Fig. 1E.

Regarding claim 22, see Fig. 2C.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 15-17, 53, 54, 60-62, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin US Patent 5,716,416.

Lin discloses the invention substantially as claimed. However, Lin does not an elastic body made of a polyurethane having at least one growth factor and/or at least one pharmacological agent (e.g. recombinant protein) dispersed in the elastic body.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the Lin reference by changing the material property of the elastic body (e.g. polyurethane) and adding growth factors to the body in order to promote the growth of cell around the implant because Applicant has not disclosed that the material property and the growth factors provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with silicone and hydrogel coatings because both materials promote the growth of tissue and both are biocompatible.

Therefore, it would have been an obvious matter of design choice to modify the Lan reference to obtain the invention as specified in the above claims.

Allowable Subject Matter

Claims 8, 9, 18, 25 and 70 are allowed.

Claims 48, 49, 51, 52, 55, and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 12 and 13 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 703-305-0277. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

A. Stewart

Alvin Stewart
May 16, 2004